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EVALUATION OF THE SUSPICIOUS ORDERS MONITORING SYSTEM FOR

Johnson & Johnson

BY

Terrance W. Woodworth

The Drug & Chemical Advisory Group, LLC

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EXECUTIVE SUMMARY

As part of its ongoing efforts to assess and improve its controlled substances procedures, specifically its suspicious orders monitoring (SOM) program, Janssen Pharmaceuticals, Inc. (Janssen) requested the assistance of The Drug and Chemical Advisory Group, LLC. (DCAG).

During the months of November and December 2017, Michele Dempsey, Janssen Director of Controlled Substances Compliance and DCAG Partner Terrance W. Woodworth interviewed key Janssen executives, managers, and customer service specialists; examined numerous Standard Operating Procedures (SOPs) and Work Instructions (WIs), and conducted a comprehensive review and evaluation of the suspicious orders monitoring program for the Janssen Ortho McNeil (JOM) Pharmaceutical Services, Inc. distribution center in Shepherdsville, Kentucky.

Additionally, during the period, December 11-13, 2017, DCAG Partner Woodworth traveled to the Johnson & Johnson (J&J) facilities in Piscataway, New Jersey and Somerset, New Jersey. On December 12, 2017, Director Dempsey and DCAG Partner Woodworth met with key Customer Service personnel at the Piscataway facility concerning their roles in the operation of the JOM suspicious orders monitoring program. On December 13, 2017, Woodworth participated in an SOM Workshop conducted by Controlled Substances Compliance Director Dempsey for key J&J stakeholders involved in the SOM program.

The DCAG evaluation found that the suspicious orders monitoring program for the JOM site in Shepherdsville, Kentucky complies with the DEA requirements set forth in Federal regulations, Title 21, Code of Federal Regulations (CFR), Section 1301.74 (b). The JOM SOM program is a multi-dimensional effort involving collaboration among personnel from JOM in Kentucky, Janssen Controlled Substances Compliance personnel, Johnson and Johnson Customer Service personnel, along with other key J&J elements. The JOM SOM program includes a new customer establishment process, a state license and DEA registration verification system, a DEA order form (DEA-222 form) examination process, a comprehensive customer SOM questionnaire, SOM SOPs and WIs, an order monitoring process with an automated order quantity threshold assessment based on an algorithm, an order investigation team, monthly SOM evaluation meetings, SOM

benchmarking exercises with industry partners, and a 'Google Alert' review process.

The DCAG review and evaluation of the JOM SOM program found that the program could be enhanced by instituting several recommendations which are more fully described in this report. However, DCAG recommends that the following suggestions be implemented as soon as possible:

1. From an executive and strategic level, continue elevating the visibility of the DEA SOM requirement within the organization and across the network of J&J companies. Provide more structure and input into the JOM SOM program by integrating the relevant corporate functions (Established Products, Value Stream Leaders for Controlled substances, Channel Operations, etc.) and experiences, even on an ad hoc or part-time basis, to provide more detailed and necessary information about customers and their controlled substance orders;

2. From a tactical and operational level, continue the JOM SOM monthly meetings. These meetings are an effective method of keeping abreast of a continuously changing SOM environment. Continue conducting an examination of how many questionable orders have been reviewed over a certain period and what were the results of the review, and continue reviewing the history of customer orders that have been 'monitored' and the circumstances. Quarterly or biannually, start convening an SOM meeting between the strategic and operational teams; and consider the creation of a separate SOM element in the Janssen organizational structure, fund it, increase the staff and define specific functions and responsibilities;

3. Start resolving the issue of possibly not applying the SOM order quantity assessment algorithm (SOM algorithm) to all customer orders for Schedule III and IV controlled substances which are received via electronic data interchange (EDI) throughout the day and night. The SOM algorithm is run against all existing controlled substances orders each day at 3:45 PM. Any orders that are received by J&J customer service via EDI after that time may be shipped to a customer the following day without being subjected to the SOM algorithm unless the EDI orders are

checked the next morning to ensure the SOM algorithm has been applied;

4. Start modifying the existing SOM algorithm and/or adding algorithms to include additional evaluation criteria for each specific DEA basic class of controlled substance handled by J&J (e.g., fentanyl, methylphenidate, tramadol). Consider a base unit of measurement, such as grams of active ingredient for the SOM algorithm(s). Consider separating J&J customers into two or more groups and perform different analyses of orders for these different groups (e.g., largest three wholesalers in one group; smaller wholesalers in another group). Consider evaluating customer orders for specific DEA basic classes of substances against similar size and geographically-placed customers, and perform national, regional, state and perhaps three-digit zip code comparisons among like size customers;

5. Start immediately providing SOM reports, including negative SOM activity reports to the State of West Virginia Board of Pharmacy (BOP). The West Virginia BOP recently established a mandatory requirement for suspicious orders reports from all wholesalers distributing controlled substances to West Virginia;

6. Start drafting a brief SOM SOP for each J&J DEA non-practitioner registrant (formulator, importer, and exporter). The SOM program for these types of DEA registrants can consist primarily of the normal regulatory requirements for the respective registrant, e.g., procurement quota requirements for the customers of the manufacturer/formulator; foreign government import or export authorizations for the importer and exporter registrants, respectively. DEA regulations require each non-practitioner registrant to establish an SOM program;

7. Consider modifying Janssen's corporate policy to include the organization's responsibility for safeguarding controlled substances and preventing their diversion (maintenance of effective controls to prevent diversion (Title 21, United States Code, Section 823) and include a summary of the SOM program; and

8. Stop using the terms 'suspicious' or 'unusual' in all Standard Operating Procedures (SOPs) and Work Instructions (WIs)

related to the corporation's SOM program; and start using another term which is a more appropriate characterization of the order evaluation process, such as 'questionable' orders or 'atypical' orders or orders 'of concern'.

BACKGROUND INFORMATION

The Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91-513), more commonly known as the "Controlled Substances Act of 1970" or "CSA", is the primary drug law in the United States which regulates controlled substances and listed chemicals. The CSA of 1970 is enforced by the U.S. Drug Enforcement Administration (DEA) and became effective on May 1, 1971 with implementing regulations which included a regulation requiring all non-practitioners (e.g., manufacturers and distributors) to operate suspicious orders monitoring programs. The regulation is Title 21, Code of Federal Regulations (CFR), Section 1301.74 (b), and reads

"The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

The suspicious orders reporting requirement provides DEA with pertinent information about potential illegal activity in a rapid manner. In the past decade, with the increasing adverse consequences of drug abuse and diversion, DEA has heightened its focus on the SOM regulation. In emphasizing its focus on SOM, DEA has held biennial industry conferences for manufacturers and distributors which included presentations on SOM. DEA has written several letters to all non-practitioner registrants discussing the details of its SOM regulation, including recommendations for detecting suspicious orders of controlled substances, and reviewing some of the DEA investigations and remedial actions the agency has taken against non-practitioner registrants, as well as, practitioner registrants. These remedial actions have included significant civil penalties, memoranda of understanding with strict compliance and reporting provisions, and revocations of the DEA registrations of non-practitioners that failed to maintain adequate controls to prevent diversion.

The controlled substance non-practitioner industry has also increased its focus on SOM matters and most firms in the industry have continued to enhance their SOM programs to detect suspicious orders for controlled substances.

DEA regulations also require the reporting to DEA of *any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical may be used in violation of the law or regulations* (21 CFR 1310.05). This DEA regulation would impact J&J's Consumer Products Division handling any ephedrine or pseudoephedrine products; however, J&J Consumer Products was not part of the DCAG evaluation.

JOM SUSPICIOUS ORDERS MONITORING PROGRAM PARAMETERS

Janssen has established an SOM program for the JOM distributor operation in Shepherdsville, Kentucky. The JOM SOM was developed in 2006 and has been continually updated and revised. In an effort to evaluate its SOM program, the Janssen Controlled Substances Compliance Director initiated a review of the JOM SOM program by DCAG and held an SOM Workshop to share experiences and knowledge of the DEA SOM requirements among key J&J participants and discuss strengths and weaknesses of the existing JOM SOM.

During the SOM evaluation process, the entire order cycle for controlled substances was reviewed by DCAG Partner Woodworth and key Janssen (J&J) personnel from the point of order receipt and entry into the SAP system, through processing, verification of all aspects of the Schedule II DEA order form (DEA Form 222), customer state license and DEA registration examination, comparison of the order quantity against an internal order quantity algorithm, subsequent investigation of any orders exceeding the algorithm quantity threshold, and the release of orders, to final shipping by JOM in Shepherdsville, Kentucky.

The JOM distribution center in Kentucky was not visited by DCAG; however, this site distributes J&J brand and authorized generic controlled substances to approximately twenty customers. These J&J controlled substance products are available in approximately ninety (90) different J&J stock keeping units (SKUs).

The JOM customers include seventeen (17) moderate size wholesalers and the three largest wholesale distributors in the United States: Cardinal Health, AmeriSourceBergen, and McKesson. These twenty customers re-distribute J&J's controlled substance products to the retail level, including doctors, pharmacies and hospitals.

These twenty customers are long term, well-established, J&J business partners; and all are wholesale distributors. Currently, there are no retail level customers such as pharmacies, doctors, or hospitals (other than the Federal organizations, such as, the Veterans Administration). These are key factors when considering the challenges associated with developing a new customer profile for a retail level registrant, establishing a retail customer's background, controlled substance ordering patterns and ascertaining legitimacy of new customer orders.

The approximately ninety (90) SKUs distributed by JOM in Kentucky consist of the following substances and products:

Schedule II:

- Methylphenidate tablets 27 mg., 36 mg., and 54 mg.;
- Concerta (methylphenidate HCl) ER tablets 18 mg., 27 mg., 36 mg., and 54 mg.;
- Fentanyl Transdermal System 12 mcg., 25 mcg., 50 mcg., 75 mcg., and 100 mcg.;
- Duragesic (fentanyl) Matrix 5x12 mcg., 5x25 mcg., 5x50 mcg., 5x75 mcg., and 5x100 mcg.;

Schedule III:

- Tylenol with Codeine tablets #3 and #4;

Schedule IV:

- Tramadol HCl ER tablets 200 mg. and 300 mg.;
- Ultracet (tramadol) tablets (2x5) x 10; 100s x 24; and
- Ultram (tramadol) ER tablets 50 mg. and 300 mg.

As noted, the SOM order review methodology includes several checks and verifications before an order for any controlled substance is fully processed. For example, J&J customer service will not process an order for any controlled substance when the DEA registration number

of the customer is not current and valid. The evaluation process also checks the drug schedule of a customer's DEA registration to ensure the customer is registered in the appropriate drug schedule for the J&J products ordered. Customer service will also not process an order for any controlled substance in Schedule II when there is any incomplete or inaccurately completed field on the DEA Order Form (DEA Form 222). These checks and verifications are also separate and additional DEA regulatory requirements that have been incorporated into JOM's SOM system, providing greater information about the customer and a given order which can be used by the SOM team to ensure legitimacy.

The JOM SOM program also takes advantage of the capabilities of its SAP software which enables the generation of several key reports that are helpful in identifying questionable aspects of an order or customer activity over selected time periods. For example, among many other possible reports, the system can facilitate a report of all controlled substance orders where the DEA registration is missing, invalid or expired, all controlled substances orders where there is an incomplete or inaccurately completed DEA Form 222, and all 'monitored' orders for controlled substances where the quantity ordered has exceeded the current threshold algorithm.

The SOM team also meets regularly, usually monthly, and discusses customer activities, drug trends, any new DEA or state-related activities that impact the JOM SOM program, and other analytical metrics that the SOM team has determined are useful in assessing its controls to prevent diversion.

The existing Janssen (J&J) methodology of centralized ordering of controlled substances and decentralized distribution of these products by JOM provides opportunities for increased communication and coordination to detect atypical orders. Currently, it appears the JOM distribution center in Kentucky is unable to independently render a final SOM determination on a given atypical order. Several different company elements, such as customer service, channel operations, established products, supply chain analysis and quality assurance possess information and perform key functions which could pertain to every controlled substance order. Each of these company elements is also cognizant of the SOM system. However, while the activities of these other corporate elements may be performed competently and expeditiously, collaboration and/or collation of indicators and possible

evidence of atypical activity involving controlled substance orders could enhance the JOM SOM.

RECOMMENDATIONS

1. From an executive and strategic level, continue elevating the visibility of the DEA SOM requirement within the organization and across the network of J&J companies. Provide more structure and input into the Janssen SOM program by integrating the relevant corporate functions (Established Products, Value Stream Leaders for Controlled substances, Channel Operations, etc.) and experiences, even on an ad hoc or part-time basis, to provide more detailed and necessary information about customers and their controlled substance orders. Corporate account directors possess key information about customers, significant activities and trends; and it is recommended that there be periodic interactions among corporate accounts, supply chain personnel, regulatory personnel, information technology staff and the quality assurance teams. It is further recommended that pertinent aspects of the extensive institutional knowledge and experience of these different corporate elements pertaining to customers and ordering patterns be shared through various team meetings, training sessions and corporate conferences;

2. From a tactical and operational level, continue the JOM SOM monthly meetings. These meetings are an effective method of keeping abreast of a continuously changing SOM environment. Continue conducting an examination of how many questionable orders have been reviewed over a certain period and what were the results of the review; and continue reviewing the history of customer orders that have been 'monitored' and the circumstances. Quarterly or biannually, start convening an SOM meeting between the strategic and operational teams; and consider the creation of a separate SOM operational element in the Janssen organizational structure, fund it, increase the staff and define specific functions and responsibilities;

3. Start resolving the issue of possibly not applying the SOM order quantity assessment algorithm (SOM algorithm) to all customer orders for Schedule III and IV controlled substances which are received via electronic data interchange (EDI) throughout the

day and night. The SOM algorithm is run against all existing controlled substances orders each day at 3:45 PM. Any orders that are received by J&J customer service via EDI after that time may be shipped to a customer the following day without being subjected to the SOM algorithm unless the EDI orders are checked the next morning to ensure the SOM algorithm has been applied;

4. Start modifying the existing SOM algorithm and/or adding algorithms to include additional evaluation criteria for each specific DEA basic class of controlled substance handled by J&J (e.g., fentanyl, methylphenidate, tramadol). Consider a base unit of measurement, such as grams of active ingredient for the SOM algorithm(s). Consider separating J&J customers into two or more groups and perform different analyses of orders for these different groups (e.g., largest three wholesalers in one group; smaller wholesalers in another group). Consider evaluating customer orders for specific DEA basic classes of substances against similar size and geographically-placed customers, and perform national, regional, state and perhaps three-digit zip code comparisons among like size customers.

   a. Stop using the current single criterion algorithm which selects and holds orders from customers when the quantity of an order is greater than three times (300 percent) the customer's average weekly order, based on a rolling twelve (12) month ordering history from that customer. This algorithm only measures quantity and does not consider frequency or a pattern of ordering by the same customer. The algorithm compares a customer's order quantity against only that customer's average annual purchases. The algorithm would not detect multiple customer orders during a given week; it would not detect orders which consist of gradual quantity increases of a controlled substance over time; it would not detect a new customer's orders for controlled substances which initially commence with larger than normal quantities and remain at a constant level. This algorithm does not distinguish between controlled substances, geographic areas, or similar size customers (e.g., similar size wholesaler).

b. If a threshold is established for a given customer or product and it proves not to be effective in accomplishing the intended purpose, it can and should be revised. When long term, well established customers' ordering patterns, frequencies, and quantities are known, thresholds can be set accordingly. It may be instructive to divide customers into defined groupings and intentionally establish thresholds at strict levels for purposes of establishing a baseline of ordering activity. It may also be effective to have more than one calculation depending on the drug product or the type of customer. These calculations can be built into SAP without need for external systems or connections. In some cases, it will be necessary for certain orders to be subjected to more extensive investigation. It is essential that the individuals and/or group (Controlled Substances Compliance) responsible for detecting suspicious orders be part of the development/modification of the calculation(s) and setting of a threshold or multiple thresholds;

5. Start immediately providing SOM reports, including negative SOM activity reports to the State of West Virginia Board of Pharmacy (BOP). The West Virginia BOP recently established a mandatory requirement for suspicious orders reports from all wholesalers distributing controlled substances to West Virginia;

6. Start drafting a brief SOM SOP for each J&J DEA non-practitioner registrant (formulator, importer, and exporter). The SOM program for these types of DEA registrants can consist primarily of the normal regulatory requirements for the respective registrant, e.g., procurement quota requirements for the customers of the manufacturer/formulator; foreign government import or export authorizations for the importer and exporter registrants, respectively. DEA regulations require each non-practitioner registrant to establish an SOM program;

7. Consider modifying Janssen's corporate policy to include the organization's responsibility for safeguarding controlled substances and preventing their diversion (maintenance of effective controls to prevent diversion (Title 21, United States Code, Section 823) and include a summary of the J&J SOM program;

8. Stop using the terms 'suspicious' or 'unusual' in all Standard Operating Procedures (SOPs) and Work Instructions (WIs) related to the corporation's SOM program; and start using another term which is a more appropriate characterization of the order evaluation process, such as 'questionable' orders or 'atypical' orders or orders 'of concern'. This recommendation is based on the Opinion of Circuit Judge Pillard in the recent (June 30, 2017) United States Court of Appeals for the District of Columbia Circuit, Denial of Petition for Review of a Final Order of the Drug Enforcement Administration, concerning Petitioner, Masters Pharmaceutical, Inc. (No. 15-1335). In his opinion, Judge Pillard noted that the DEA Administrator, using the definition of 'suspicion' in Black's Law Dictionary, "reviewed Masters' SOMS manual and determined that any order held by the Computer Program was held due to its unusual size, frequency, or pattern, and DEA regulations expressly provide that deviations in size, frequency, or pattern are the sort of indicia that give rise to a suspicion and, unless the suspicion is dispelled, the obligation to report"....."whenever an order for controlled substances was held by the SOMS Computer Program, that order was presumptively suspicious under 21 CFR 1301.74 (b); and Masters' employees rarely undertook the investigation to dispel the suspicion surrounding the held orders";

9. Continue using and merging other DEA regulatory requirements into your SOM and expand/automate certain verifications, if possible (Customer's DEA number, state license number, drug schedules and business activity, etc.). Consider meeting with DEA's Registration and Regulatory Support Section and determine whether it is feasible to perform a monthly DEA and State license verification and thus automate these verification processes and possibly upload DEA registrations and state licenses daily;

10. Start enhancing the JOM SOM program; and be more assertive in the implementation of the JOM SOM in the context of enhancing customer relationships;

    - Increase SOM related data collection and analysis. Utilize IntegriChain data, data from Value Centric's Value Trak 852 and 867 EDI programs to evaluate and/or verify customer inventory levels and activities;

- Evaluate the usefulness of IMS data, particularly for planned future retail activities;
- Consider including ARCOS historical purchase data to assist in establishing customer trends;
- Determine the feasibility of using State Prescription Drug Monitoring Program (PDMP) data (if available);
- Evaluate chargeback data and information in J&J's possession, and determine if any of the data or information is of value to the goals and objectives of the JOM SOM program. If the chargeback data and information are useful, then consider monthly or quarterly, completing runs of all chargeback data by distributor by drug class by pharmacy (with quantities) and compare with a run of all pharmacies controlled substance purchases without regard to the distributor that submitted the chargeback. Consider using chargeback data to assist in evaluating regional distribution trends for J&J controlled substance products. If appropriate, consider eliminating chargebacks for select products and/or customers;
- Continue the SOM team's interaction with internal stakeholders, e.g., Brand Teams on pharmacy communications, SOM education and compliance; seek greater data and information from retail chains (i.e. basis for your distributor's order) with detailed breakdown by store number or another identifier);

11. Continue improving J&J's relationship with its customers; consider shortening the SOM questionnaire for customers to the specific information required to effectively manage the JOM SOM; initiate periodic SOM meetings or conference calls with your distributors; if possible, visit each wholesale customer and develop a better understanding of their SOMs; collaborate on further SOM initiatives on difficult issues (the greater the risk of improper customer activity, the greater requirement for more detailed information to aid in decision making);

12. Continue enhancing J&J training initiatives and workshops concerning SOM requirements and processes; explain the exposure vulnerabilities and possible consequences of system weaknesses and failures; and acknowledge that a valid and reliable SOM system is not static and requires continuous adjustment and fine-tuning;

- Training exercises could include actual situations and reviews of past questionable customer transactions that were examined by the SOM team and resolved;
- When an SOM related action against a DEA registrant is noted; determine whether there is a 'learning' from that case; determine whether it involves one of J&J's customers, and, if so, whether the JOM SOM algorithm identified any previous atypical orders for that customer; and modify the algorithm accordingly;
- Take past order examples and evaluate their circumstances, order patterns and activity against revised algorithm(s) to determine discrepancies or adjustments needed;

13. Start updating your SOM SOPs with additional elements and enhancements, including new data sources that are being used and additional information that will be evaluated. Expand the procedures for documenting and reporting a suspicious order to DEA, including to whom the report should be furnished, what information should be included in the report, which J&J employee should make the report and in what form or forms (verbal initially, followed with written report). It appears that the JOM SOM has not reported an order for controlled substances as suspicious during its time in operation;

14. Start planning for an enhanced J&J new customer establishment process with a view toward retail level customers. The new customer SOP should include questions designed to ascertain the nature of a potential customer's business, which products will be ordered from J&J, for what purposes, and the estimated quantities and frequency; and, if possible, from which vendor were these products ordered previously. An effective SOM program includes due diligence efforts in evaluating and approving new customers and ensuring that existing customers continue to meet their obligations in properly handling controlled substances;

15. Consider establishing a retail SOM specialty team in preparation for the launch of Esketamine, and conduct various distribution model evaluations;

16. Continue efforts to improve J&J's relationship and reputation with DEA, state and local authorities, the National Association of State Controlled Substances Authorities (NASCSA), the National Association of Boards of Pharmacy (NABP), the National Association of Model State Drug Laws (NAMSDL), the National Alliance of PDMP, the National Association of Drug Diversion Investigators (NADDI) (also NADDI State Chapters), and the International Association of Chiefs of Police (IACP). These are key regulatory and law enforcement agencies, in addition to FDA, that are involved in controlled substance diversion and abuse prevention. Increased J&J participation at conferences and key industry meetings held by these organizations, as well as, regular interaction with these organizations would be beneficial;

17. Consider funding certain controlled substance abuse and/or prevention initiatives. Meet with DEA in key geographic areas; share your SOM program procedures; and strive to continue enhancing J&J's relationship with DEA Diversion Program Managers and Group Supervisors in Louisville, San Juan, Newark and at DEA headquarters);

18. Consider special SOM related initiatives/actions in geographic areas of concern, as well as, in assisting customers improve their controlled substances handling procedures (hospitals);

19. Contact State PDMP managers and discuss collaboration and possible provision of J&J sales data or other exchange of controlled substances information.

NEAR TO MID TERM OBJECTIVE

During the SOM Workshop conducted on December 13, 2017, there was discussion of the possibility of establishing an upfront assessment of all customer controlled substance orders by customer size, and quantity and drug class ordered to determine a customer specific set of values or criteria that would enable an expeditious initial decision on the order; and then follow this initial decision with a more detailed analysis and evaluation of the order and customer retrospectively. The objective would be to have an initial "atypical" order determination

at the time the order is created. This was an excellent discussion and it is recommended that the issue be pursued.

STANDARD OPERATING PROCEDURES AND WORK INSTRUCTIONS REVIEWED DURING THE SOM EVALUATION

1. DS-SOP-1235 JOM Customer Support Services Schedule II-V Order Processing and Investigating Suspicious or Excessive Orders

2. DS-SOP-1251 JOM Customer Service Customer Master Data Process

3. DS-WI-1662 JOM Customer Services - Business Manager Release Orders

4. DS-WI-3815 JOM Customer Support Services Order Processing of Controlled Substances

5. DS-WI-3824 JOM Customer Support Services DEA Unusual Order Report and Monitoring Process

6. DS-WI-30472 JOM Customer Support Services New Customer Request Process

7. DS-JOB-959 JOM Customer Service New Customer Pre-Application

8. DS-JOB-960 JOM Customer Service New Customer Post Application

Contact Information

Terrance W. Woodworth
The Drug and Chemical Advisory Group
4911 Heversham Court
Fairfax, VA 22032
(703) 569-8740 Office
(703) 395-0009 Mobile
(703) 455-6190 Fax
twoodworth@thedcag.com